



NDA 21-064/SLR-001

CBE-0 SUPPLEMENT

Bristol-Myers Squibb Medical Imaging, Inc.
Attention: James M. Adie
331 Treble Cove Road
North Billerica, MA 01862

Dear Mr. Adie:

Please refer to your supplemental new drug application dated February 4, 2002, received February 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DEFINITY™.

This "Changes Being Effected" (CBE-0) supplemental new drug application provides for the correct volume of 1.5 mL for the vial and carton final printed labeling.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Medical Imaging and Radiopharmaceutical Drug Products (HFD-160) and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5600 Fishers Lane, HFD-42
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
FDA
5600 Fishers Lane, HF-2
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Thuy M. Nguyen, M.P.H., Regulatory Health Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader for the
Division of Medical Imaging and
Radiopharmaceutical Drug Products (HFD-160)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Eldon Leutzinger
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